



**Telix Pharmaceuticals Limited**  
ACN 616 620 369  
55 Flemington Road  
North Melbourne  
Victoria, 3051  
Australia

## ASX ANNOUNCEMENT

### **FDA Accepts NDA for TLX101-Px (Pixclara®)**

Melbourne (Australia) and Indianapolis, IN (U.S.) – April 10, 2026. Telix Pharmaceuticals Limited (ASX: TLX, NASDAQ: TLX, “Telix”) today announces that the United States (U.S.) Food and Drug Administration (FDA) has accepted the Company’s resubmitted New Drug Application (NDA) for TLX101-Px<sup>1</sup>, (Pixclara®<sup>2</sup>, Floretyrosine F 18 or <sup>18</sup>F-FET), an investigational PET<sup>3</sup> agent for the imaging of glioma (brain cancer), and has assigned a PDUFA<sup>4</sup> goal date of September 11, 2026.

The approval of TLX101-Px will fulfil a significant unmet medical need for the characterization of recurrent or progressive glioma from treatment related changes in both adult and pediatric patients<sup>5</sup>. Neuroimaging of glioma with <sup>18</sup>F-FET is already broadly recommended in international clinical practice guidelines – including NCCN Guidelines®<sup>6</sup> – and TLX101-Px has been granted Orphan Drug<sup>7</sup> and Fast Track<sup>8</sup> designations by the FDA.

“There remains a critical unmet need in improving our ability to image residual glioma after treatment,” said Thomas Hope, MD, Vice Chair, Department of Radiology and Biomedical Imaging, University of California, San Francisco (UCSF). “We have worked with Telix for the last three years to help leverage our clinical data to help make FET-PET<sup>9</sup> available to patients in the United States.”

Patrick Wen, MD, E. Antonio Chiocca, MD, PhD, Family Endowed Chair in Neuro-Oncology at Mass General Brigham Cancer Institute, added, “Distinguishing tumor progression from treatment-related change remains one of the most challenging aspects of glioma care. PET imaging with <sup>18</sup>F-FET is an important tool in clinical practice worldwide, and the FDA’s acceptance of this application is a meaningful step toward broader access for patients and clinicians in the United States.”

Kevin Richardson, CEO, Telix Precision Medicine, added, “The FDA’s acceptance of our NDA resubmission is an important milestone for Telix. We appreciate the FDA’s constructive engagement and look forward to working closely with the Agency to urgently obtain approval and then bring this product to market for the benefit of patients.”

Telix’s FY 2026 financial guidance does not include any revenue contribution from TLX101-Px.

#### **About TLX101-Px**

TLX101-Px is a PET imaging candidate, which has been granted Fast Track and Orphan Drug designations by the FDA for the characterization of recurrent or progressive glioma from treatment related changes. TLX101-Px targets membrane transport proteins known as L-type amino acid

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<sup>1</sup> Telix’s NDA was resubmitted on March 13, 2026. Telix ASX disclosure March 16, 2026.

<sup>2</sup> Brand name subject to final regulatory approval.

<sup>3</sup> Positron emission tomography.

<sup>4</sup> Prescription Drug User Fee Act.

<sup>5</sup> Subject to FDA review and approval.

<sup>6</sup> Galldiks et al. *Lancet Oncol.* 2025 (Joint guidelines from the European Association of Nuclear Medicine (EANM), European Association of Neuro-Oncology (EANO), Society of Nuclear Medicine and Molecular Imaging (SNMMI), Response Assessment in Neuro-Oncology (RANO), The European Society for Pediatric Oncology and The Response Assessment in Pediatric Neuro-Oncology for the characterization of recurrence in glioma patients); National Comprehensive Cancer Network® (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Central Nervous System Cancers V1.2025.

<sup>7</sup> Telix ASX disclosure October 6, 2020.

<sup>8</sup> Telix ASX disclosure April 16, 2024. Fast Track is a process designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier. More: <https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track>

<sup>9</sup> Positron emission tomography imaging with Floretyrosine F 18.

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transporters 1 and 2 (LAT1 and LAT2). This enables TLX101-Px to be potentially utilized as a patient selection and response assessment tool for Telix's LAT1-targeting therapy candidate TLX101-Tx (iodofalan <sup>131</sup>I), currently under investigation in the pivotal IPAX-BrIGHT trial in patients with recurrent glioblastoma<sup>10</sup>. TLX101-Px and TLX101-Tx have not received marketing authorizations in any jurisdiction.

## About gliomas

Gliomas are diffusely infiltrative tumors that affect the surrounding brain tissue. They are the most common form of central nervous system (CNS) cancer that originates from glial cells, accounting for approximately 30% of all brain and CNS tumors and 80% of all malignant brain tumors<sup>11</sup>. In the U.S., there are approximately 24,000 new glioma cases diagnosed annually<sup>12</sup>. Glioblastoma (GBM) is a high-grade glioma and the most common and aggressive form of primary brain cancer. The mainstay of treatment for GBM comprises surgical resection, followed by combined radiotherapy and chemotherapy. Despite such treatment, recurrence occurs in almost all patients<sup>13</sup>, with an expected survival duration of 12-15 months from diagnosis<sup>14</sup>.

## About Telix Pharmaceuticals Limited

Telix is a global biopharmaceutical company focused on the development and commercialization of radiopharmaceuticals with the goal of addressing significant unmet medical need in oncology and rare diseases. Telix is headquartered in Melbourne (Australia) with international operations in the United States, United Kingdom, Brazil, Canada, Europe (Belgium and Switzerland) and Japan. Telix is listed on the Australian Securities Exchange (ASX: TLX) and the Nasdaq Global Select Market (NASDAQ: TLX).

Visit [www.telixpharma.com](http://www.telixpharma.com) for further information about Telix, including details of the latest share price, ASX and U.S. Securities and Exchange Commission (SEC) filings, investor and analyst presentations, news releases, event details and other publications that may be of interest. You can also follow Telix on [LinkedIn](#), [X](#) and [Facebook](#).

### Telix Investor Relations (Global)

Ms. Kyahn Williamson  
SVP Investor Relations and Corporate  
Communications  
[kyahn.williamson@telixpharma.com](mailto:kyahn.williamson@telixpharma.com)

### Telix Investor Relations (U.S.)

Ms. Annie Kasparian  
Director Investor Relations and  
Corporate Communications  
[annie.kasparian@telixpharma.com](mailto:annie.kasparian@telixpharma.com)

### Telix Investor Relations (Australia)

Ms. Charlene Jaw  
Associate Director Investor  
Relations  
[charlene.jaw@telixpharma.com](mailto:charlene.jaw@telixpharma.com)

## Media Contact

Eliza Schleifstein  
917.763.8106 (Mobile)  
[Eliza@schleifsteinpr.com](mailto:Eliza@schleifsteinpr.com)

*This announcement has been authorized for release by the Telix Pharmaceuticals Limited Disclosure Committee on behalf of the Board.*

Legal Notices

*Cautionary Statement Regarding Forward-Looking Statements.*

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<sup>10</sup> ClinicalTrials.gov ID: [NCT07100730](https://clinicaltrials.gov/ct2/show/study/NCT07100730).

<sup>11</sup> Goodenberger et al. *Cancer Genet.* 2012.

<sup>12</sup> CBTRUS Statistical Report: Primary Brain and Other Central Nervous System Tumors Diagnosed in the United States in 2018-2022. *Neuro-Oncology.* 2025.

<sup>13</sup> Park et al. *Journal of Clinical Oncology.* 2010.

<sup>14</sup> Ostrom et al. *Neuro Oncol.* 2018.

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*You should read this announcement together with our risk factors, as disclosed in our most recently filed reports with the Australian Securities Exchange (ASX), U.S. Securities and Exchange Commission (SEC), including our Annual Report on Form 20-F filed with the SEC, or on our website.*

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